

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

[Handwritten signature]

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
5 July 2001 (05.07.2001)

PCT

(10) International Publication Number
WO 01/47443 A1

(51) International Patent Classification⁷:

A61F 2/44

(21) International Application Number:

PCT/US00/32337

(22) International Filing Date:

27 November 2000 (27.11.2000)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

09/471,312 23 December 1999 (23.12.1999) US

(71) Applicant and

(72) Inventor: SAZY, John, A. [US/US]; 3217 Omega Drive, Arlington, TX 76014 (US).

(74) Agents: GUNTER, Charles, D. et al.; Felsman, Bradley, Vaden, Gunter & Dillon, L.L.P., Suite 1600, 201 Main Street, Fort Worth, TX 76102 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

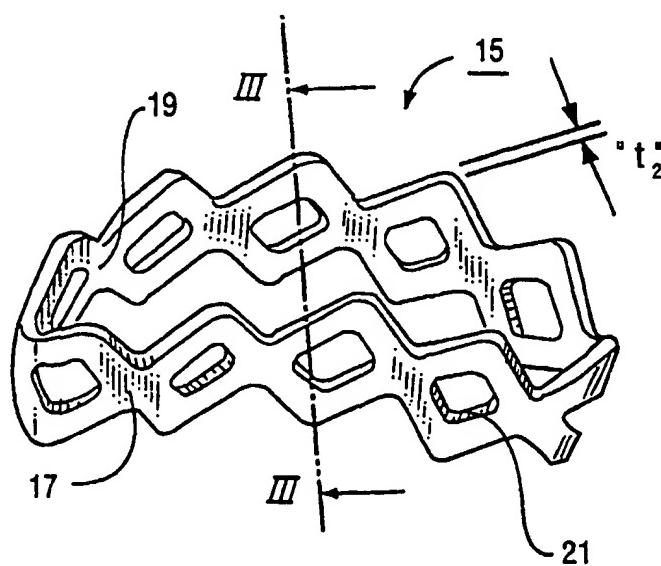
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— With international search report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTERVERTEBRAL CAGE AND METHOD OF USE



(57) Abstract: An intervertebral prosthesis (15) for implantation between adjacent vertebrae of the human spine is shown. The prosthesis is formed as a unitary cage body configured and sized to be inserted between adjacent vertebrae in a single step implantation procedure. The cage body is banana shaped as viewed from above, the body having an exterior surface (17) and an interior surface (19), the interior surface defining an internal recess for receiving cancellous bone material during an implantation procedure. The cage body can be formed as an interlinked mesh.

WO 01/47443 A1

- 1 -

INTERVERTEBRAL CAGE AND METHOD OF USE

Description

Technical Field

The present invention relates generally to a human spinal implant device for implantation into intervertebral space between adjacent vertebral bones and to a surgical method for installing such a spinal implant assembly.

Background Art

Genetic or developmental irregularities, trauma, chronic stress, tumors, and degenerative wear are typical causes which can result in spinal pathologies for which surgical intervention is necessary. Various devices and techniques are disclosed in the prior art for immobilizing and\or fusing adjacent bones by implanting artificial devices in or on the spinal column. The region of the back which needs to be immobilized, as well as the individual variations in anatomy, determine the appropriate surgical protocol and implantation device which is best suited for the case at hand. Where a failure of the intervertebral disc is concerned, the inter-body fusion implant is often chosen.

An inter-body fusion maintains disc height, helps to protect the nerve root and restores weight-bearing ability to anterior structures. The fusion also restores the annular region of the spine to tension and immobilizes the unstable, degenerated intervertebral disc. Anterior approaches and fusion in the cervical region have gained wide acceptance by both neurosurgeons and orthopedic surgeons as treatment for herniated discs, trauma and related degenerative conditions. In the case of lower lumbar spine problems, such techniques have had more sporadic success. Recently, pedicel screws and rods have allowed surgeons to reduce degenerative conditions and immobilize the motion segment, but

- 2 -

have not eliminated the need for weight-bearing support for the anterior spinal column.

5 The prior art implant techniques have generally involved two component implant assemblies. The surgical procedures for installing such devices can be complicated and traumatic to the patient. Although X-ray imaging can be used to determine the approximate location of the respective two component assemblies, alignment of the prostheses can obviously be of major concern.

10

Accordingly, it is an object of the present invention to provide a new and improved single component inter-body fusion cage which overcomes known deficiencies of the prior art while providing improved overall results.

15

- 3 -

Disclosure of Invention

The apparatus of the invention is an intervertebral prosthesis for implantation between adjacent vertebrae of the human spinal column. The prosthesis comprises a unitary body configured and sized to be inserted between adjacent vertebrae in a single step implantation procedure. The body is banana-shaped as viewed from above and has an exterior surface and an interior surface, the interior surface defining an internal recess for receiving cancellous bone material during an implantation procedure. Preferably, the unitary body is a cage which is formed as interlinked mesh. Most preferably, the banana-shaped cage body is a ring of metal having evenly spaced openings about a circumference of the body. The preferred cage body is formed of a hard metal alloy, such as a titanium alloy. The intervertebral prosthesis is selectively sized to fit within a vertebral disk space of a human anatomy allowing adequate space for additional cancellous bone anterior to the cage body within the disk space.

The method of the invention facilitates inter-body fusion in the vertebral column by providing an improved prosthesis and method of installation. A space is first prepared for receiving a prosthetic device between two vertebrae. The banana-shaped spinal cage body is then surgically inserted into the space between the vertebrae. The banana-shaped cage body has an exterior surface and an interior surface, the interior surface defining an internal recess for receiving cancellous bone material during an implantation procedure. Preferably, the cage body is a ring of metal having evenly spaced openings about a circumference of the body. The cage body forms an interlinked mesh. The preferred cage body is formed of a hard metal alloy. Preferably, the cage body is formed of a titanium alloy.

Additional objects, features and advantages will be apparent in the written description which follows.

- 4 -

Brief Description of Drawings

Figure 1 is a simplified side view of the human anatomy, showing the spinal process;

5

Figure 2 is a close up, perspective view of the spinal implant of the invention;

10 Figure 3 is a cross sectional view of the spinal implant of Figure 2, taken along line II-II, and illustrating the cross-sectional thickness of the device of the invention;

Figure 4 is a top view of the banana-shaped device of the invention showing certain of the dimensions thereof;

15

Figure 5 is a perspective view of two of the prior art devices used as spinal prostheses;

20 Figure 6 is a top, simplified view of the banana-shaped cage of the invention in place upon the lumbar vertebrae of the human anatomy;

25 Figure 7 is a similar view showing the placement of cancellous material within and anterior to the banana-shaped implant of the invention;

Figure 8 shows the placement of prior art devices within the vertebral region;

30 Figure 9 illustrates the possible misalignment of the prior art devices in the vertebral space and schematically illustrating the possibility of asymmetric forces acting upon the device;

35 Figure 10 is an isolated view of the intervertebral cage of the invention in place within the vertebral space;

- 5 -

Figure 11 is a simplified side view showing the placement of the cage of the invention within the vertebral space;

5 Figure 12 is a posterior view of the human spinal column showing placement screws which are used during the discectomy process;

10 Figure 13 is a side, partial perspective view of the human spinal column showing the use of an expansion tool to spread the L-4 and L-5 vertebrae;

15 Figure 14 is a side, partial cross-sectional view of the human spine, showing the removal of tissue to prepare the disc space for receiving the prosthesis of the invention;

Figure 15 is a posterior view of the spinal region showing the installation of the banana-shaped prosthesis of the invention;

20 Figure 16 is a view similar to Figure 15 but showing the insertion of additional cancellous bone material within the disc space anterior to the cage implant;

25 Figure 17 is a view similar to Figure 13 but showing the use of the compression tool to compress the installed prosthesis and associated vertebrae;

30 Figure 18 is a simplified detail view of the insertion of the cage of the invention, illustrating the curved disc space and removed tissue;

Figure 19 is a detail side view illustrating the placement of the cage of the invention within the intervertebral space; and

35 Figure 20 is a back view showing the placement of the cage within the disc space.

- 6 -

Best Mode for Carrying Out the Invention

The bones and connective tissue of an adult human spinal column consists of more than 20 discrete bones coupled sequentially to one another by a tri-joint complex which consists of an anterior disc and the two posterior facet joints, the anterior discs of adjacent bones being cushioned by cartilage spacers referred to as intervertebral discs.

These more than 20 bones are anatomically referred to as being members of one of four classifications: cervical, thoracic, lumbar, or sacral. The cervical portion of the spine, which comprises the top of the spine, up to the base of the skull, includes the first 7 vertebrae. The intermediate 12 bones are the thoracic vertebrae and connect to the lower spine comprising the 5 lumbar vertebrae. The base of the spine is the sacral bones. The component bones of the cervical spine are generally smaller than those of the thoracic spine, which are in turn smaller than those of the lumbar region. The sacral region connects laterally to the pelvis. Figure 1 is a simplified schematic of the human anatomy showing the spinal column 11 and intervertebral disc space 13 which, in this case, is at approximately the L4-L5 location.

The spinal column of bones is highly complex, serving to house and protect critical elements of the nervous system having countless peripheral nerves and circulatory bodies in close proximity. Surgical procedures are therefore delicate and demanding by their very nature. In the case of spinal pathologies for which surgical intervention is necessary, particularly with respect to failure of the intervertebral disc, the interbody fusion implant has found acceptance in the field because such devices can be implanted into the anterior of the spine and maintain disc height, protect the nerve root and restore weight bearing ability to the anterior structures. Typically a pair of elements were implanted. The elements themselves were sometimes

- 7 -

cylindrical or tubular bodies, solid plugs or cage designs, to mention a few. The present invention is directed to an improved unitary cage and method for its installation.

5 Figure 2 shows the implant device of the invention, designated generally as 15. In the preferred embodiment illustrated, the unitary body 15 is a cage configured and sized to be inserted between adjacent vertebrae in a single step implantation procedure. As shown in Figures 2 and 4, the cage 15 is "banana-shaped" as view from above. The body has an exterior surface 17 and an interior surface 19. The interior surface 19 defines an internal recess or enclosure for receiving cancellous bone material during an implantation procedure. The preferred cage body, as best seen in Figure 2, is a ring having evenly spaced
10 openings 21 about a circumference of the body. The double bands form a serpentine arrangement which comprises an interlinked mesh
15 in the preferred embodiment shown in Figure 2.

A preferred material for the cage body 15 is a hard metal
20 alloy, preferably titanium or stainless steel. Other preferred materials include carbon fiber, bioreabsorbable materials such as polyglycotic acid, polylactic acid and other synthetic materials such as polymethylmethacrylate PMMA blended with various antibiotic admixtures for the treatment of discitis and vertebral
25 osteomyelitis.

The cage body is selectively sized to fit within a vertebral disc space of a human anatomy allowing adequate space for additional cancellous bone anterior to the cage body within the
30 disc space. Referring to Figures 3 and 4, the cage 15 is typically provided in a range of widths "w" of 24mm, 26mm and 28mm. The lengths "l" are typically 8mm, 9mm and 10mm. The heights are 10mm, 12mm, 14mm and 16mm. The thickness of the titanium "t1" is approximately 1.5mm. The thickness of the mesh material "t2" is approximately 2mm. The radius of curvature "R1" of the front arc
35 of the cage is approximately 1.5mm. The radius of curvature "R2"

- 8 -

of the posterior or back arc of the cage is approximately 1.5mm.

The unitary cage 15 can be placed from an anterior position (anterior interbody fusion or ALIF), or posteriorly (posterior lumbar interbody fusion or PLIF, transforaminal interbody fusion or TLIF). The cage is curved so that it mirrors the natural radius or curvature of the anterior and posterior curves of the vertebral bodies. It can be placed from an anterior position or posterolateral position after standard discectomy.

10

Figure 5 shows a prior art pair of bone implants. In the discussion which follows, the advantages of the unitary cage of the invention will be apparent with respect to the prior art rings 23, 25. Figure 6 shows the banana-shaped cage of the invention 15 within the disc space, as view from above. Note that the cage 15 is curved so that it mirrors the natural radius of curvature of the anterior and posterior curves of the vertebral bodies. Figure 7 is merely intended to illustrate the placement of cancellous bone material 27, 29 both within the cage 15 and anterior thereto. Figure 8 illustrates the proper placement of the prior art bone rings 23, 25, as viewed from above. Figure 9 illustrates the possible misalignment of the prior art rings 23, 25 due to the two component nature of the procedure as well as the possibility of asymmetric forces acting upon the rings. Figure 10 is an illustration of the cage prosthesis 15 of the invention inserted within the intervertebral disc space 31. Figure 11 is a side view of the disc space 31 showing the proper placement of the cage of the invention.

30

The steps in a standard discectomy will be familiar to those skilled in the art. However, the steps will be briefly summarized below and with respect to Figures 12-17. In the case of a transforminal lumber interbody fusion and spondylosis thesis at L5 S1, the patient's left and right side are first detached parallel to the muscles in prone position. A wide exposure is carried out to the tips of the transverse processes. Resection of

- 9 -

the facet joints L5 S1 on both sides is then performed. The pedicle is opened, as by means of an awl and the pedicle channel is probed. The pedicle is then tapped and screws are inserted. Figures 12 and 13 shows the screws 33,35,37 in place. The screws 5 33,35,37 in the L4, L5 and S1 positions are aligned by means of a head adjuster so that the screws are aligned in one plane. Rods 39,41 are then placed (see Figure 12). The rods 39, 41, in the particular procedure illustrated are fixed by means of inner screws 43 and outer nuts 45.

10

As illustrated schematically in Figure 13, segmental distraction is then applied between S1 and L5 while a simultaneous posteriorly directed force at the cephalad end of the rod is carried out. The same procedure is then performed on the opposite 15 side of the body. Resection and removal of the facet is the first step to achieve access to disk L5 S1 via the transforminal approach. This may be carried out with the use of a high speed bur or a pituitary ronjour. The medial portion of the facet joint can be resected by chisel and removed. Removal of the cephalad 20 section of the S1 facet is accomplished, allowing enough space for the later placement of the implant prosthesis. Removal to the plane of the S1 pedicle but not into the pedicle may be carried out. By doing this, additional widening of the transforminal approach is established. Removal of the disk itself may be 25 accomplished by means of straight and angled pituitary ronjous.

Proper resection of the postural lips of L5 S1 implants should be carried out. Additional spreading of the disk space is achieved by use of a wedge shaped impactor and specifically 30 designed dilators. Further reduction of deformity is achieved by means of segmental distraction forces on both sides.

Disc space preparation is next carried out with the use of the cup curet with teeth (43 in Figure 14) for cartilage removal 35 and preservation of the implants. Further removal of any disk fragments is also carried out in this step of the procedure.

- 10 -

Spongiosa and any additional morcilized graft can now be inserted to the anterior longitudinal ligament and anterior third of the disk space L5 S1. The spongiosa is condensed by the use of specially designed impactors.

5

The properly sized cage implant of the invention can now be selected as determined by the height of the disk space after reduction. Figure 15 illustrated the insertion of the banana-shaped cage 15 of the invention within the disc space 31, the cancellous bone material 29 also being visible. Figure 16 shows the placement of additional cancellous bone material in the region surrounding the cage implant 15.

15 The nuts at L5 are now untightened. The conversion of the previously applied distractive forces are converted to compression forces by means of a compressor (45 in Figure 17). This procedure is repeated alternatively on both sides. A final tightening sequence is then performed on the screws for rod-stabilization and maintenance of the desired correction. Additional application of 20 bone for posterior lateral fusion may be accomplished as shown with respect to Figure 16. The conversion of distraction forces to compression forces after positioning of the implant 15 allows restoration of both the tension band principle and load-sharing principle within the fused segment.

25

Figure 18 is an additional view of the insertion of the cage 15 of the invention within the disc space showing the curved nature of the disc space. Figures 19 and 20 are side and back views, respectively, of the properly placed cage.

30

An invention has been provided with several advantages. The unitary banana-shaped cage of the invention is easier and safer to place within the prepared disc space and is mechanically more stable than the previous two component systems currently in use. 35 The curvature of the cage of the invention mirrors the natural curvature of the anterior and posterior curves of the vertebral

- 11 -

bodies.. It can be placed from either the anterior position or posterolateral position after standard discectomy. The implant of the invention can be manufactured from a variety of materials including both metals, metal alloys and synthetic, bioreabsorbable
5 materials.

While the invention has been shown in only one of its forms, it is not thus limited but is susceptible to various changes and modifications without departing from the spirit thereof.

- 12 -

Claims

What is claimed is:

- 5 1. An intervertebral prosthesis for implantation between adjacent vertebrae of the human spine, comprising:

a unitary body configured and sized to be inserted between adjacent vertebrae in a single step implantation procedure;

10 wherein the unitary body is banana shaped as viewed from above, the body having an exterior surface and an interior surface, the interior surface defining an internal recess for receiving cancellous bone material during an implantation procedure.

- 15 2. An intervertebral prosthesis for implantation between adjacent vertebrae of a human spine, comprising:

20 a unitary cage body configured and sized to be inserted between adjacent vertebrae in a single step implantation procedure;

25 wherein the cage body is banana shaped as viewed from above, the body having an exterior surface and an interior surface, the interior surface defining an internal recess for receiving cancellous bone material during an implantation procedure; and

wherein the cage body forms an interlinked mesh.

- 30 3. The intervertebral prosthesis of Claim 2, wherein the cage body is selectively sized to fit within a vertebral disk space of a human anatomy allowing adequate space for additional cancellous bone anterior to the cage body within the disk space.

- 13 -

4. The intervertebral prosthesis of Claim 2, wherein the cage body is a of metal having evenly spaced openings about a circumference of the body.

5 5. The intervertebral prosthesis of Claim 4, wherein the cage body is formed of a hard metal alloy.

6. The intervertebral prosthesis of Claim 5, wherein the cage body is formed of a titanium alloy.

10 7. A method for providing vertebral inter-body fusion in the vertebral column, the method comprising the steps of:

15 preparing a space for receiving an orthopedic prosthetic device between two vertebrae;

20 surgically inserting a unitary cage body into the space between the vertebrae, wherein the cage body is banana shaped as viewed from above, the body having an exterior surface and an interior surface, the interior surface defining an internal recess for receiving cancellous bone material during the implantation procedure and wherein the cage body forms an interlinked mesh.

25 8. The method of Claim 7, wherein the cage body is selectively sized to fit within a vertebral disk space of a human anatomy allowing adequate space for additional cancellous bone anterior to the cage body within the disk space.

30 9. The method of Claim 8, wherein the cage body is a ring of metal having evenly spaced openings about a circumference of the body.

10. The method of Claim 9, wherein the cage body is formed of a hard metal alloy.

- 14 -

11. The method of Claim 10, wherein the cage body is formed of a titanium alloy.

5

10

15

20

25

30

35

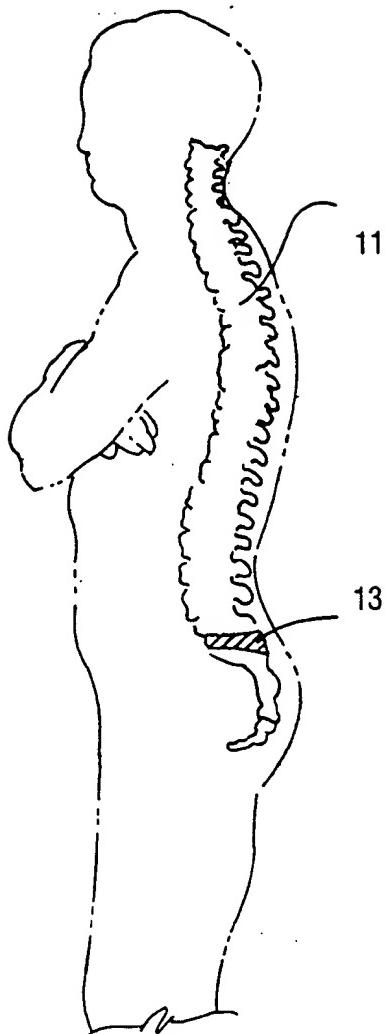


FIG. 1

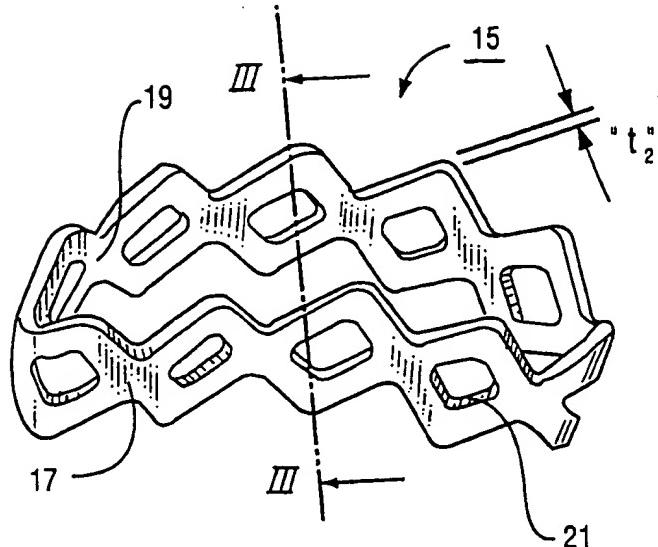


FIG. 2

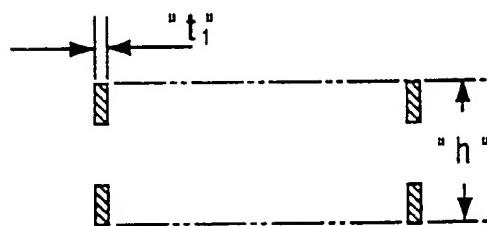


FIG. 3

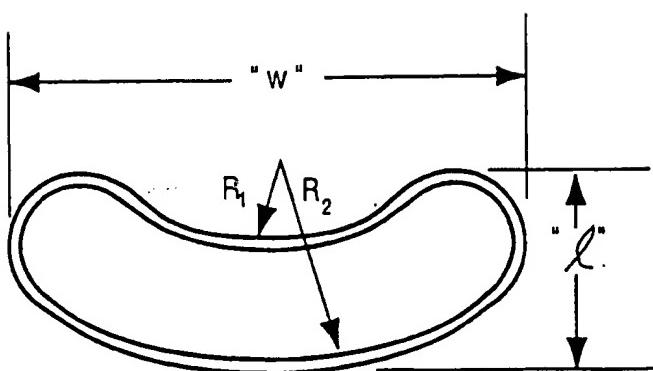


FIG. 4

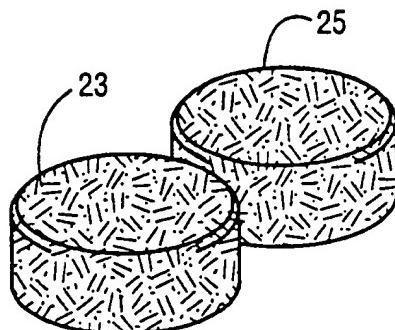
FIG. 5
PRIOR ART



FIG. 6

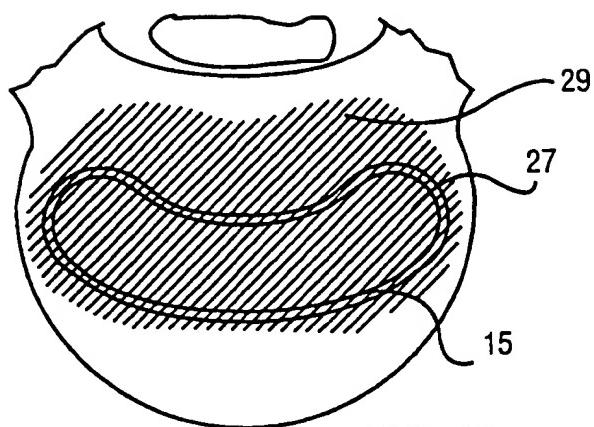


FIG. 7

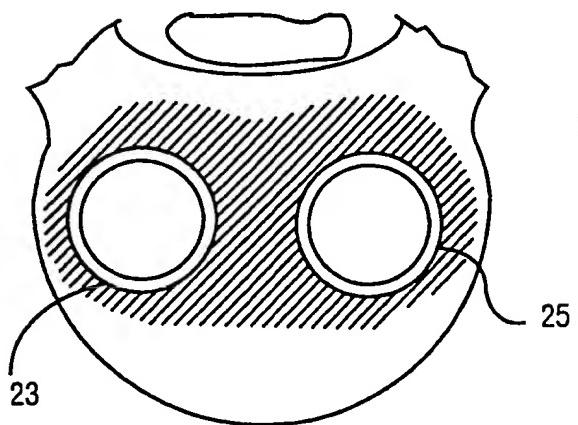
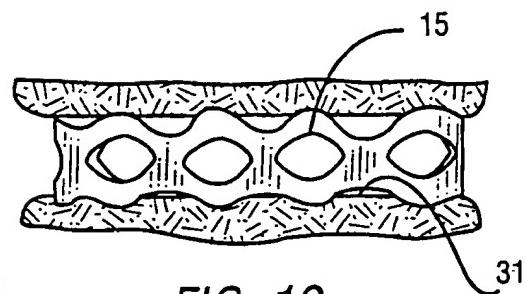
FIG. 8
PRIOR ART

FIG. 10

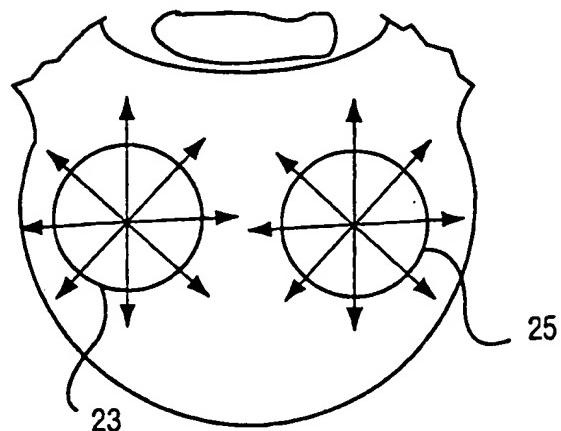
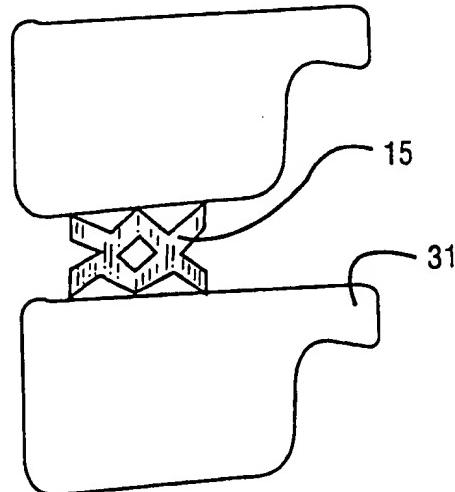
FIG. 9
PRIOR ART

FIG. 11

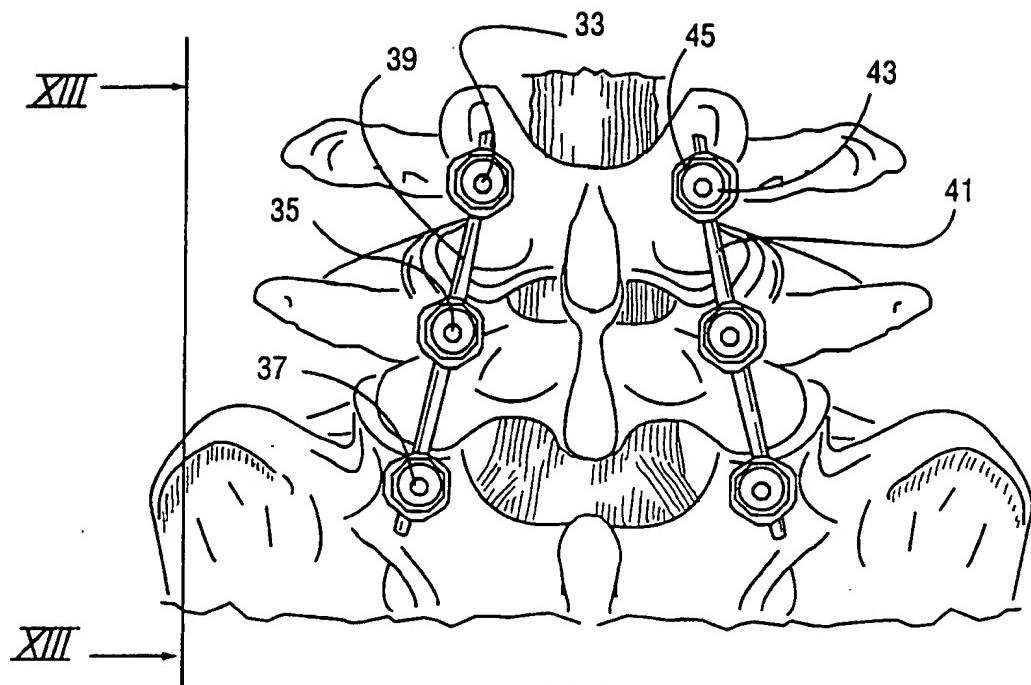


FIG. 12

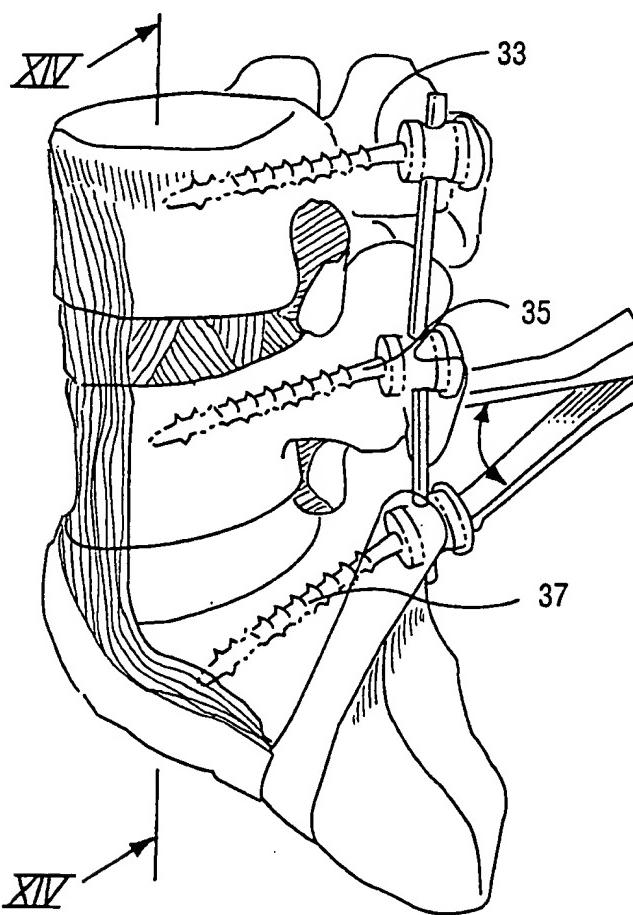


FIG. 13

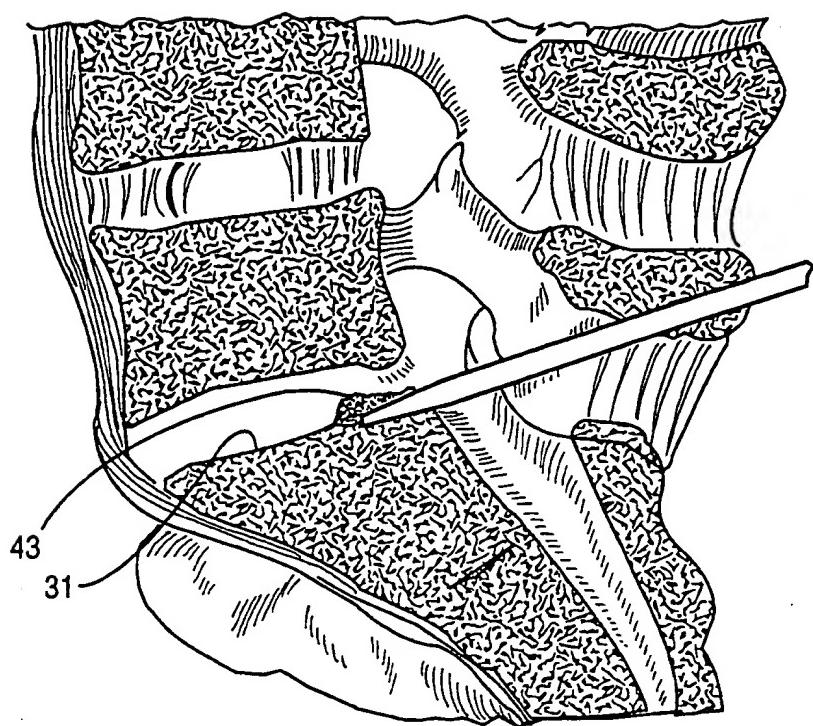


FIG. 14

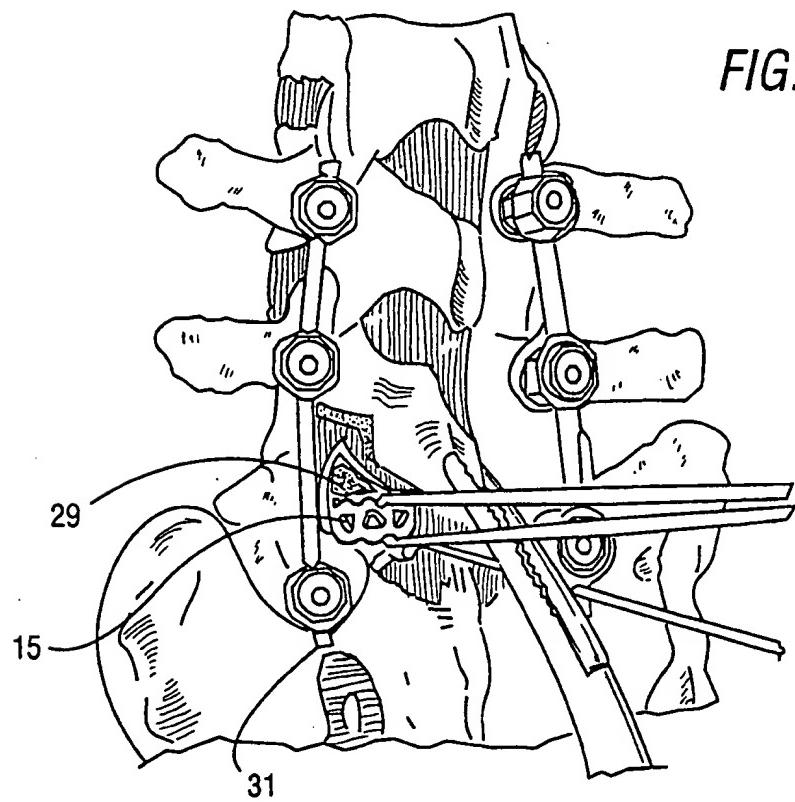


FIG. 15

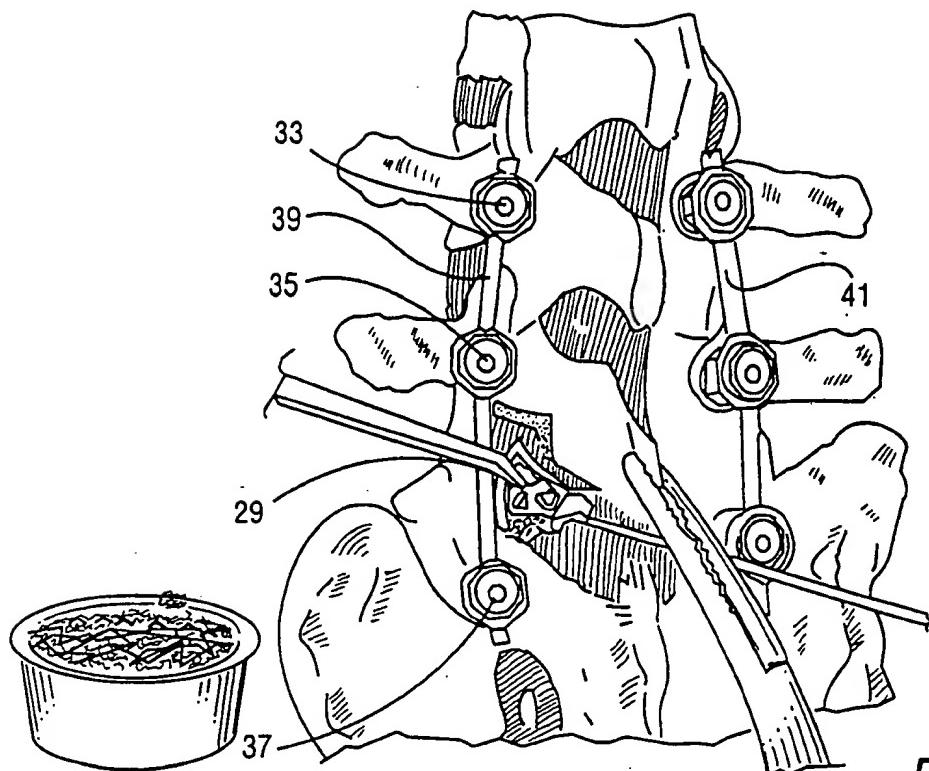


FIG. 16

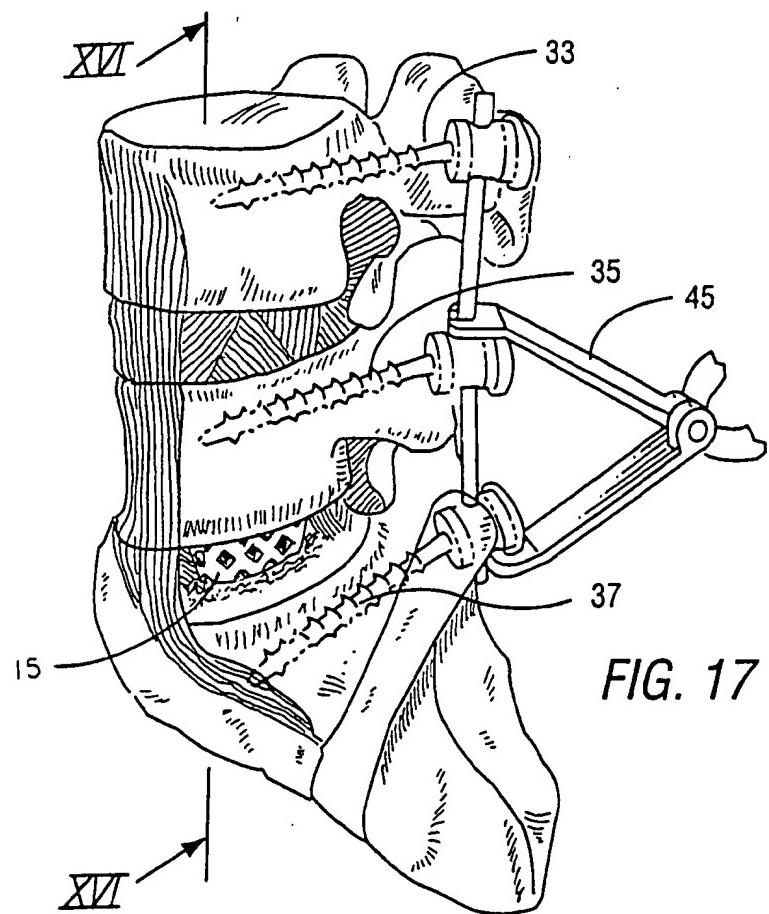


FIG. 17

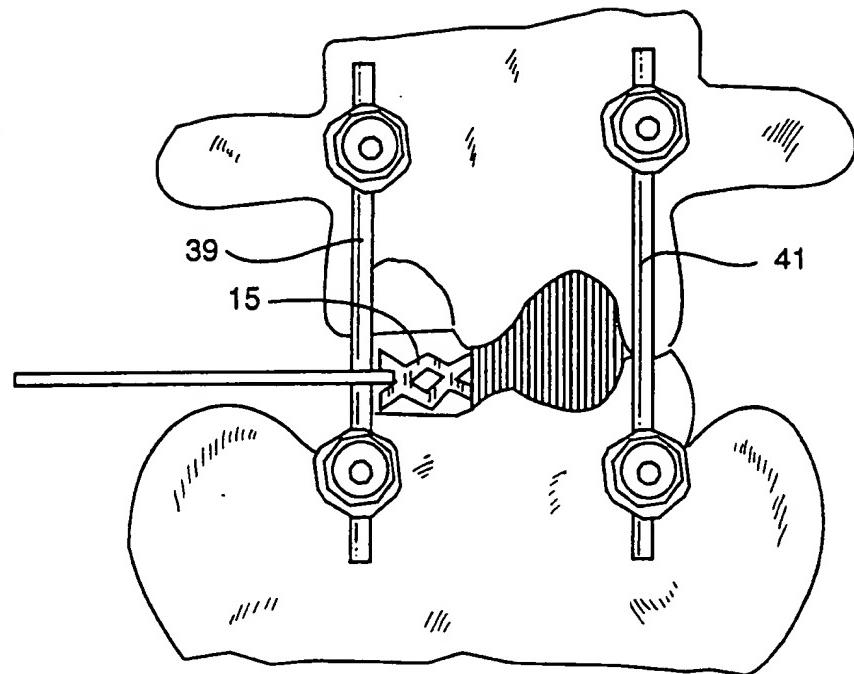


FIG. 18

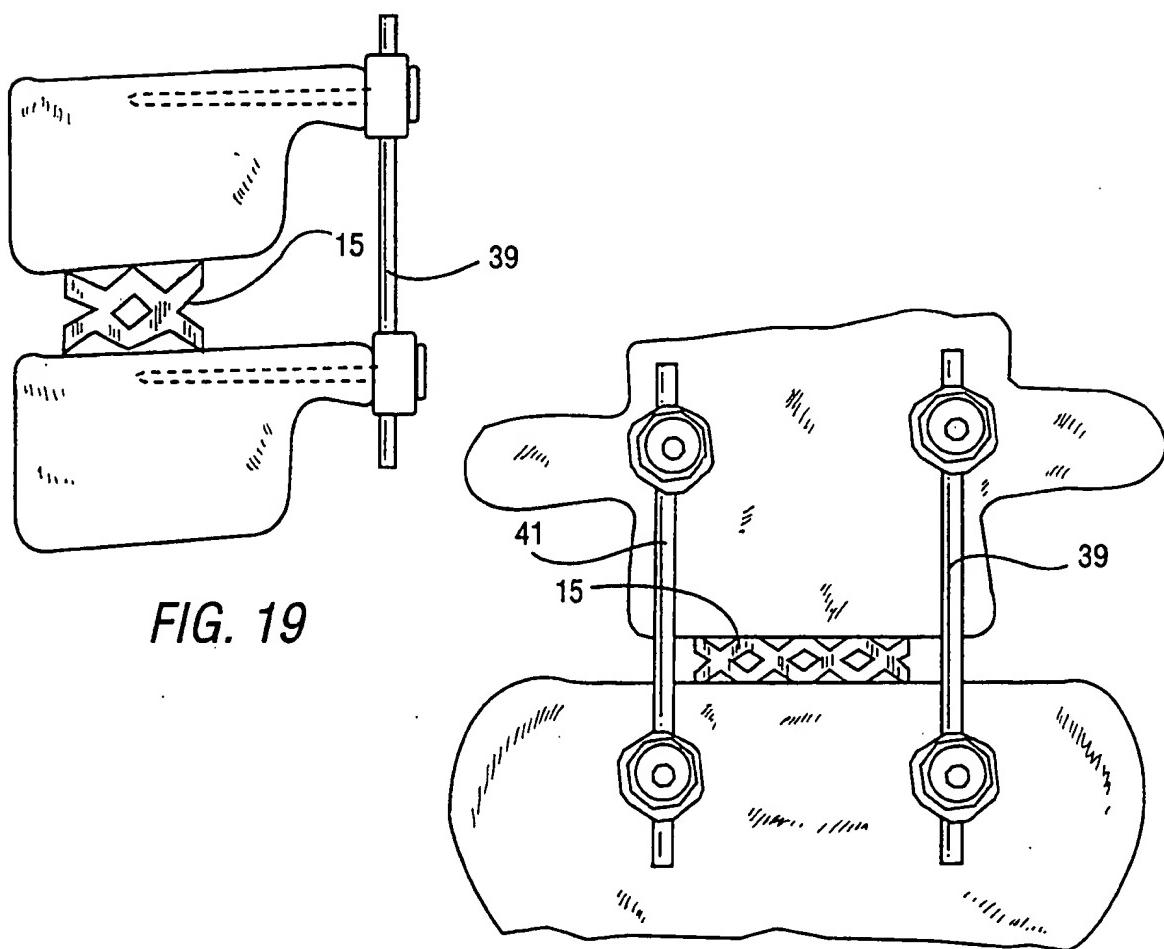


FIG. 19

FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/32337

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/44

US CL : 623/17.11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17.11, 17.16, 23.53, 23.54, 23.63, 908

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST search terms: bone, cage, vertebrae, kidney shape, cavity

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3,867,728 A (STUBSTAD et al.) 25 February 1975, col. 5, lines 40-46 and 48-49; col. 14, lines 17-34 and Figs. 17, 23 and 24.	1-11
Y	US 5,609,637 A (BIEDERMANN et al.) 11 March 1997, col. 2, lines 6-8 and Figs. 2, 3 and 5.	1-11
A	US 5,827,289 A (REILEY et al.) 27 October 1998, Figs. 11 and 14; col. 6, lines 27-29 and 35-39; and col. 14, lines 1864.	1, 2, 7, 8
Y	US 5,702,449 A (McKAY) 30 December 1997, Figs. 1, 3 and 8-11; col. 4, lines 5-13 and 33-42; and col. 5, lines 28-38.	1-11

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

02 JANUARY 2001

Date of mailing of the international search report

26 JAN 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer
BRIAN PELLEGRINO

Telephone No. (703) 306-5899